Medical Device Tracking

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What's the Point? Introduction

- To make sure the devices can be located quickly.
- To make sure that manufacturers (hospitals) have a system to locate their devices promptly.

Who Has to Track?

- Manufacturers (hospitals) and distributors.
- FDA will issue an “order” (a letter) to a manufacturer (hospital) that identifies what device(s) must be tracked.

What Is a Tracking Order?

- A Tracking Order means FDA has told the manufacturer (hospital) it must maintain current information on the location of certain devices.

Can FDA Issue a Tracking Order for Any Device?

NO!

FDA may require tracking for a class II or class III device if:

A) failure would have serious adverse health consequences;

B) it is intended to be implanted in the human body for over one year; or

C) it is life sustaining or life supporting and used outside a clinical facility.

Are There Other Criteria That FDA Considers Before It Decides Whether a Device Should Be Tracked?

YES !

A) likelihood of sudden catastrophic failure (such as mechanical heart valves),

B) likelihood of significant adverse clinical outcome, and

C) need for prompt professional intervention.

What Is a Manufacturer Supposed to Do When It Receives a Tracking Order?

A manufacturer that receives a tracking order must develop and start a tracking program to track information about devices that go to distributors, hospitals, and patients.

What Devices Are "Tracked" in the United States?

- FDA has issued tracking orders to manufacturers for the following implantable devices:
  - Temporomandibular joint (TMJ) prosthesis
  - Glenoid fossa prosthesis
  - Mandibular condyle prosthesis

- Implantable pacemaker pulse generator
- Cardiovascular permanent implantable pacemaker electrode
- Replacement heart valve (mechanical)
- Automatic implantable cardioverter/defbrillator

- Implanted cerebellar stimulator
- Implanted diaphragmatic/phrenic nerve stimulator
- Implantable infusion pump
- Dura mater
- Abdominal aortic aneurysm stent graft

FDA Has Issued Orders to Manufacturers for the Following Devices Used Outside a Device Clinical Facility:

- Breathing frequency monitor
- Continuous ventilator
- Ventricular bypass (assist) device
- DC-defribrillator and paddles
- Infusion pump (electromechanical only)

Each Manufacturer (Hospital) May

- Develop its own tracking program, or
- Hire an outside firm to conduct a tracking program.

However, the manufacturer or importer is still responsible for the tracking program.

What Kind of Information Must Be Produced to FDA in 3 Days, As Required by "Tracking"?

When FDA has ordered the recall of certain devices, the manufacturer must supply the name, address, and telephone number of all distributors and the location of product not distributed.

What Kind of Information Must Be Produced to FDA in 10 Days, As Required by "Tracking"?

- Patient information:
  - Device identification
  - Shipment date
  - Name, address, telephone number of patient – and Social Security Number

- Date provided to patient
- Name, mailing address and telephone number of prescribing physician
- Name, mailing address, and telephone number of managing physician
- Date of explant, death or destruction

When Would FDA Ask for Tracking Information?

When FDA orders a manufacturer (hospital) to recall a product because there is a reasonable probability the device could cause serious, adverse health consequences or death, and the firm is NOT willing to recall the device voluntarily.

Manufacturers (hospitals) can use tracking information from the tracking program when they conduct voluntary recalls.

The information can help recall product more quickly.

Patients have the legal right to refuse to have information about them released for the purposes of tracking. This is a privacy issue.

However, the manufacturer still must make a record that the device was distributed and implanted.

When a Firm Goes Out of Business, What Happens to the Tracking Information?

- The firm is required to notify FDA.
- If another firm buys the right to make or distribute the tracked device, that buyer becomes responsible for tracking.

- If the firm just stops making or distributing the tracked device, it still must track those devices it previously distributed.
- If the firm goes completely out of business with no surviving operation or buyer, FDA must receive the tracking information.

How Often Has FDA Ordered a Manufacturer to Conduct a Recall and to Produce Tracking Information?

Never!

Manufacturers eventually see the light !

Guidance on Medical Device Tracking

www.fda.gov/cdrh/modact/tracking.pdf